

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to radiopharmaceuticals

The Board of Pharmacy hereby amends Chapter 16, “Nuclear Pharmacy Practice,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 147.76.

Purpose and Summary

This amendment requires nuclear pharmacies to comply with the minimum standards identified in United States Pharmacopeia General Chapter 825, which applies to radiopharmaceuticals and will be effective December 1, 2020.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on September 23, 2020, as **ARC 5194C**. The Board received one comment, which was in support of the amendment but suggested a grace period for compliance. Given the limited number of nuclear pharmacies impacted by the amendment and the Board’s established waiver process available, the Board declined the suggested revision. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on November 17, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on February 3, 2021.

The following rule-making action is adopted:

Amend subrule 16.4(6) as follows:

16.4(6) *Compliance ~~with laws~~*. Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs. Nuclear pharmacies shall comply with all standards identified in United States Pharmacopeia General Chapter 825.

[Filed 11/30/20, effective 2/3/21]

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/30/20.